

St. Francis Medical Center

A St. Francis Affiliated Health Service
Sponsored by the Franciscan Missionaries of Our Lady Health System

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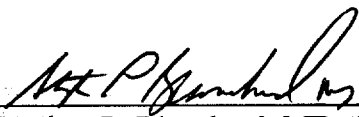
August 5, 1999

Documents Branch
Food and Drug Administration
5630 Fishers Lane #1061
Rockville, MD 20852

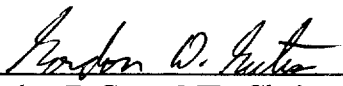
It has come to our attention that there is consideration being given by the Food and Drug Administration to requiring a hepatitis C lookback all the way back to the inception of transfusion therapy. We at St. Francis Medical Center are hard at work to complete the lookback to 1988 which is the current FDA requirement and we believe that this is sufficient to meet the needs of our patients. We are baffled by the reportedly planned requirement to use an outdated test for the determination of chronic infection.

In light of the fact that roughly five percent of the American people at large test positively for hepatitis C and there is no effective therapy for the chronic infection, it seems pointless to go back more than twelve years for transfusion recipients. Unless we are going to create a policy of testing all patients for hepatitis C as we once did for syphilis there is really little benefit for going back further than we are presently doing. The further back we go the fewer patients will be locatable and the more will have died. Unless cost is no object and universal testing is thought to be worth the effort, we believe that we will have done enough by going back to 1988.

We urge you to leave the requirement for retrospective evaluation as it is.



Stephen P. Blanchard, MD, Chairman
Infection Control Committee



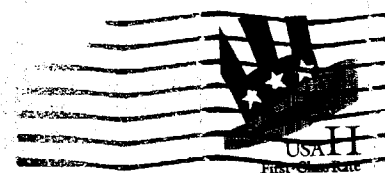
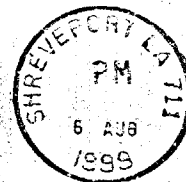
Gordon D. Gates, MD, Chairman
Infection Control Focus Group

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P. O. Box 1901
309 Jackson Street
Monroe, LA 71210-1901 • 318-327-4000

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